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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,000	03/31/2004	Chunlin Yang	DEP-5286	1332

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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10/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,000	Applicant(s) YANG ET AL.	
	Examiner Agnes B. Rooke	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 15-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to a bone graft composition, classified in class 530, subclass 350.
- II. Claims 15-23, drawn to a method for the preparation of mineralized collagen particles, classified in class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention I can be made by a process that is distinct from invention II that can encompass different steps and can have different mode of operation. Therefore, the inventions are distinct.

Also, there would be an undue burden to the examiner to search both of the distinct inventions at the same time, since searching of invention I would not include searching of invention II because distinct search strategies would have to be applied.

Applicant is advised that for the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes B. Rooke whose telephone number is 571-272-2055. The examiner can normally be reached on Mon-Fri/ Max Flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

During a telephone conversation with Mr. Skula on p/13/2007, a provisional election was made without traverse to prosecute the invention of Group I, claim 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Status of Claims

Claims 1-23 are pending.

Claims 1-14 are under consideration, Claims 15-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Priority

No priority is claimed.

IDS

Information Disclosure Statement was filed on 6/7/2004 and was reviewed and signed by examiner.

Drawings

Drawings filed on 3/31/2004 were accepted by the draftsman.

Objections

Claim 4 is objected to because in line 3, a comma is necessary after the word "mediators."

Claim 8 is objected to because it depends from itself.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "substantially uniformly distributed" is indefinite because it is not certain what is the level of uniformly distributed collagen in a graft. Also, no definition or indication of level is provided in the specification. Dependent claims 2-14 are included in this rejection because they do not further cure the deficiencies of the independent claims. Thus, clarification is required.

In claim 4, the phrase "thrombin derived peptides" is indefinite since there is no definition in the specification that would define or explain such terms.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 9, 11, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. U.S. 2002/0183855.

Yamamoto et al. teach porous matrix that comprises mineralized fibrillar insoluble collagen (See [0014]) and to form a porous fixed tissue repair matrix, the mineralized biopolymer fibers are mixed with a binder. (See [0024]). The binders include gelatin, carboxymethylcellulose, and hyaluronic acid. (See [0026]). (claims 1, 2, and 14).

The matrix material can be combined with an osteogenic material, such as autogenous bone or autologous aspirated bone marrow, or osteoinductive bone growth

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factors, BMP's, or other growth factors. (See [0037]). (instant claim 3, 4, 5, 8, and 9 where sodium hyalurane is a form of hyaluronic acid).

The mineralized collagen will be in the range from about 0.1 to 10 weight percent. (See [0017]) (instant claims 6, 11, 12). Yamamoto et al. also teach that the amount of collagen present in the mineralized product will generally be from about 95% to 30% based on the weight of collagen fibers exclusive to the binder. (See [0023]) (instant claim 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 7, 10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. U.S. 2002/0183855 in view of Silver et al. U.S. 5,532,217.

The teachings of Yamamoto are disclosed above where they do not teach diameters for collagen fibers.

Silver et al. in column 2, lines 19-25 teach a bone replacement structure that has demineralized matrix and where the collagen fibers can have diameter of less than a micron and up to several millimeters. (claims 7, 10, and 13 of the instant invention).

Also, the collagen fibers with such diameters will form mineralized intact collagen fibers with subfibrillar substructure.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a graft that has properties as taught by Yamamoto et al. and to have collagen particles with diameters as disclosed by Silver et al. because the collagen fibers with diameters of the instant invention will work effectively in a graft design and it will successfully form an intact collagen fibers with subfibrillar structure in the are of interest, and thus such a graft would be predictable to work successfully with this particle size.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have

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any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR




KATHLEEN KERR BRAGDON, PH.D.
SUPERVISORY PATENT EXAMINER